



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2020-N-0002]

New Animal Drugs; Withdrawal of Approval of Abbreviated New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of an abbreviated new animal drug application (ANADA) at the sponsor's request because the product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Hikma International Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118, has requested that FDA withdraw approval of ANADA 200-323 for use of a 1-gram bolus of phenylbutazone in horses because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of ANADA 200-323, and all supplements and amendments thereto,

is hereby withdrawn, effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Elsewhere in this issue of the *Federal Register*, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: July 15, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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